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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/346,794	07/02/1999	TERRY P. SNUTCH	NMEDP001-2	2888

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EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/02/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/346,764 Applicant(s) Snutch et alExaminer
Nirmal S. BasiArt Unit
1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 22, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-33 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

1. Amendment filed 4/22/02 (paper number 20) has been entered.

Claim Rejection, 35 U.S.C. 112, second paragraph

2. Claim 25-27 and 31-33 remain rejected, for reasons of record, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Further claims 25, 28-31 are newly rejected.

Upon further consideration claims 25, 28, and 31 are newly rejected for being indefinite because the name T-type calcium channel α_1 subunits does not sufficiently describe the α_1 subunit of a mammalian T-type calcium channel . Claims 25, 28, and 31 are indefinite because the name “ α_1 subunit” of a mammalian T-type calcium channel has not been defined in the claims and specification so as to allow the metes and bounds of the claims to be determined. The specification discloses, “The terms “ α_1 subunit” or “ α_1 calcium channel” refer to a protein subunit of a calcium channel which is responsible for pore formation and contains the voltage sensor and binding sites for calcium channel agonists and antagonists. Such subunits may be independently functional as calcium channels or may require the presence of other subunit types for complete functionality”. The terms “ α_1 subunit” has been defined only in general functional terms and lacks structural information so as to allow the metes and bounds of the claim to be determined. It is not clear which polypeptide sequences would be considered “ α_1 subunit of a mammalian T-type calcium channel”, and considering the applicants definitions of “ α_1 subunit” it is not clear what determines what “protein

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subunit of a calcium channel which is responsible for pore formation”, what are the binding sites for calcium channel agonists and antagonists, so as to allow the metes and bounds of the claims to be determined. Further the term “ α_1 subunit” also encompasses subunits encoded by DNA molecules “which hybridize under conditions of medium (or higher) hybridization stringency with one or another of the specific sequences disclosed in this application”. It is not clear what is the structure of said “ α_1 subunit”. Therefore, name “ α_1 subunit of a mammalian T-type calcium channel” does not sufficiently serve to characterize said subunit. Prior art does not disclose the structure of the isolated α_1 subunit.

Applicant argues the basis of the rejection is somewhat puzzling and, “as described in the specification, the basic structure of calcium channels in general is well known in the art (see, for example, page 3, first paragraph)”. Applicants arguments have been fully considered but not found persuasive. Claim 25 and dependent claims 26-27 remain indefinite because the preamble recites “A method of identifying compound which behaves as an agonist for a T-type mammalian calcium channel, but the claim does not state how the goal of the preamble is achieved. It is not clear what activity is determined and how an agonist is identified. An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved. In instant case steps 2 and 3 are not clearly defined. The specification, page 3, first paragraph, nor the claims disclose the structure of T-type calcium channel alpha 1 subunits. Further it is not clear what activity is measured and how that activity identifies the compound as an agonist.

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Claim 28 is newly rejected because it is not clear what activity is measured so as to allow the metes and bounds of the claim to be determined.

Claim 31 remains indefinite because it is not what determines if a compound is an agonist or antagonist and how the conclusion that what was stated in the preamble was achieved.

5 Compounds may bind to the alpha 1 subunit and be neither agonist or antagonist. It is not clear how the method differentiates between compounds that bind and have no effect as compared to those which may be agonists and antagonists.

Claim 32 is indefinite because it is not clear how the determination of competitive binding determines if a compound is an agonist or antagonist. It is not clear how competitive binding will

10 determine if the compound is an agonist or antagonist.

Claim 33 is indefinite because it is not clear how the label is provides and what are "equilibrium binding measurements", so as to allow the metes and bounds of the claim to be determined. Further it is not clear how "equilibrium binding measurements" determine if a compound is an agonist or antagonist.

15 In response to Applicants arguments as pertaining on pages 5 and 6 of paper number 20, the methods of claims 25-33 all measure agonist or antagonist activity. The methods all require contacting of t-type mammalian calcium channel with a test compound. When a compound is determined to be an agonist a specific activity is measured. When a compound is determined to be an antagonist it must be shown to antagonize the effects of an agonist. It is not clear for example

20 how contacting a compound with the calcium channel will determine if it is an antagonist or agonist.

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Just measuring one effect without correlation with a standard will not produce the results required by methods claimed.

Claim 29 and 30 are newly rejected for dependence on a rejected base claim.

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph

5 The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Applicant arguments have been fully considered. Applicant argues, "It is both described in the specification and known in the art that T-type calcium channels are associated with a multiplicity of conditions, and that blocking the activity of these channels or activating them will have, therefore, an effect on these conditions. Terrance Snutch discloses T-type activity is associated with a number of cardiac conditions including pacemaker activity, cardiac hypertrophy hypertension, abnormal T-type calcium function is also associated with neurological disease, impaired fertility and agonists and antagonists of T-type calcium channels are useful in treating these conditions. Snutch also states the

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“particular T-type calcium channel involved I a particular condition may depend on its tissue distribution”. The specification discloses, “The present invention relates to novel mammalian (including human) calcium channel compositions, and to the expression of these compositions in cell lines for use in evaluating calcium channel function and the behavior of compositions which modulate calcium channel function”. The response of the Applicant nor the specification disclose the function of the novel α subunits (α_{IG} , α_{IH} and α_{II} subunits) which relate to the present invention.

Claim 25-33 remain rejected, for reasons of record, and as indicated below, under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

A “specific utility” is a utility that is specific to the subject matter claimed, as opposed to a “general utility” that would be applicable to the broad class of the invention. A “substantial utility” is a utility that defines a “real world” use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities. A “well established utility” is a utility that is well known, immediately apparent, or implied by the specification’s disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A “well established utility” must also be specific and substantial as well as credible.

Based on the record, there is not a “well established utility” for the claimed invention.

The isolated α_1 subunit of a mammalian T-type calcium channel is required to practice the claimed invention. Prior art does not disclose isolated α_1 subunit of a mammalian T-type calcium

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channel and their effect on a specific dysfunction. Applicant has asserted utilities for the " α_1 subunit of a mammalian T-type calcium channel". For example, the specification at page 1 asserts that, "The present invention relates to novel mammalian (including human) calcium channel compositions, and to the expression of these compositions in cell lines for use in evaluating calcium channel function and behavior of compositions which modulate calcium channel function". Further stated is, "In addition to the variety of normal physiological functions mediated by calcium channels, they are also implicated in a number of human disorders". The specification, in Table 5, discloses the electrophysical and pharmacological properties of known α_1 subunits of calcium channels which have been "cloned to date". The α_1 subunits are associated with calcium channels of the type L, N, and P/Q. The present invention, "provides sequences for novel mammalian calcium channel subunits of T-type calcium channels", which are labeled as α_{1G} , α_{1H} and α_{1I} subunits". The specification states that "these subunits, either alone or assembled with other proteins, can produce functional calcium channels, which can be evaluated in model cell lines to determine the properties of the channels containing the subunits of the invention. These cell lines can be used to evaluate the effects of pharmaceuticals and /or toxic substances on calcium channels incorporating α_{1G} , α_{1H} and α_{1I} subunits" (page 7). The specification discloses polynucleotide encoding " α_1 subunit" may be useful as probes in screening human cDNA libraries for genes encoding these novel calcium channel subunits, the α_1 subunit may be used to generate antibodies, cell lines expressing α_1 subunit may be used to evaluate compounds as pharmacological modifiers of the function of novel calcium channel subunits, (page 8). Further disclosed novel calcium channel subunits may be associated with

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a human genetic disease including, but not limited to; epilepsy, migraine, ataxia, hypertension, arrhythmia, angina, depression, small lung carcinoma. Lambert-Eaton syndrome, characterization of such associations and ultimately diagnosis of associated diseases can be carried out with probes which bind to the wild-type or defective forms of the novel calcium channels (page 9).

5 The utilities asserted by Applicant are not substantial or specific. Neither the specification nor the art of record disclose any disease states treatable by the novel polynucleotides, of instant invention, or polypeptides encoded by them. Similarly, neither the specification nor the art of record disclose any instances where blocking any effects of said polynucleotides or polypeptides encoded by them reduces the effect of a disease state. Thus the corresponding asserted utilities are essentially

10 methods of treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use especially when the complete sequence of the claimed invention is not known. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real

15 world" context of use for the disclosed polynucleotides or the polypeptides encoded by them, further experimentation is necessary to attribute a utility to the claimed polynucleotides and encoded polypeptides. See *Brenner v. Manson*, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing", and stated, in context of the utility

20 requirement, that "a patent is not a hunting license. It is not a reward for the search, but

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compensation for its successful conclusion."). Since the utilities asserted by Applicant for polynucleotide and polypeptide of instant application are not substantial or specific, then it follows that the method of claim 21 (method of identifying compounds capable of acting as agonists or antagonists for T-type mammalian calcium channels), also has no utility. Similarly, agonists and antagonists identified by said method have no utility.

4. Claims remain 25-33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Further, even if one of skill in the art were enabled to use the instant method, one would not be enabled to practice the method as broadly claimed because the general structural attributes definitive of α_1 -subunit for T-type calcium channels are not taught in the specification, nor known in the art (also see rejection under 35 U.S.C. 112, second paragraph above). One would be enabled to make T-type channels using only the instant α_{1G} , α_{1H} or α_{1I} subunits. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi

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July 1, 2002

Michael D. Pak
MICHAEL PAK
PRIMARY EXAMINER